510(K) SUMMARY

MAY 1 6 2014

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

The assigned 510(k) number is: K132037.

1. **Submitter:**

Shenzhen Mindray Bio-medical Electronics Co., LTD
Mindray Building, Keji 12th Road South, Hi-tech Industrial Park,
Nanshan, Shenzhen, 518057, P. R. China

Tel: (86)755-81888998
Fax: (86)755-26582680

Contact Person:

Yanhong Bai
Manager Regulatory Affairs
SHENZHEN MINDRAY BIO-MEDICAL ELECTRONICS CO., LTD.
Mindray Building, Keji 12th Road South, High-tech Industrial Park,
Nanshan, Shenzhen 518057, P.R. China
Tel: (86) 755-81885635
Fax: (86) 755-26582680
E-mail: baiyanhong@mindray.com

Date Prepared:

May 13, 2014

2. **Name of the devices:** Accutorr 3 Vital Signs Monitor

Classification

21 CFR 870.2300 Cardiac monitor (including cardiotachometer and rate alarm)	Class II
21 CFR 870.2700 Oximeter	Class II
21 CFR 870.1130 Noninvasive blood pressure measurement system	Class II
21 CFR 880.2910 Clinical electronic thermometer	Class II

3. **Device Description:**

The Accutorr 3 Vital Signs Monitor is a compact, easy-to-use vital signs monitor designed to satisfy basic monitoring needs. It consists of a main unit, parameters measurement accessories, peripheral equipments or accessories.

The Accutorr 3 Vital Signs Monitor is designed to monitor a fixed set of physiological parameters including Pulse Oxygen Saturation (SpO2), Pulse Rate(PR), Non-invasive Blood Pressure (NIBP) and Temperature (TEMP). This monitor provides 3 different SPO2 modules manufactured by Mindray, Masimo or Nellcor.

4. Intended Use:

The monitor is intended for spot-check monitoring physiologic parameters, including SpO2, PR, NIBP and TEMP, on adult, pediatric, and neonatal patients in healthcare facilities by clinical physicians or appropriate medical staff under the direction of physicians.

5. Predicate Devices:

The Accutorr 3 Vital Signs Monitor is substantially equivalent to the predicate device VS-800 Vital Signs Monitor (K072235). They have the same intended uses, the same technological characteristics, and are comparable in key safety and effectiveness features.

6. Non-clinical Tests:

The Accutorr 3 Vital Signs Monitor has been evaluated for biocompatibility, safety, parameter performance and electromagnetic compatibility, and has been designed to comply with applicable medical safety standards. This device has been tested and evaluated under the following standards:

- ISO 14971 Medical device - Application of Risk Management to Medical Devices
- IEC 60601-1 Medical Electrical Equipment, Part 1: General Requirements for Safety
- IEC 60601-1-2 Medical electrical equipment part 1-2: General requirements for safety - Collateral standard: Electromagnetic compatibility- Requirements and tests
- IEC 60601-1-4 Medical electrical equipment - Part 1-4: General requirements for safety - Collateral Standard: Programmable electrical medical systems
- ISO 9919 Medical electrical equipment - Particular requirements for the basic safety and essential performance of pulse oximeter equipment for medical use
- EN 1060-1 Specification for Non-invasive sphygmomanometers - Part 1: General requirements
- EN 1060-3 Non-invasive sphygmomanometers - Part 3: Supplementary requirements for electro-mechanical blood pressure measuring systems

- EN 1060-4 Non-invasive sphygmomanometers-Part 4: Test procedures to determine the overall system accuracy of automated non-invasive sphygmomanometers
- ANSI/AAMI SP-10 Manual, electronic, or automated sphygmomanometers
- ASTM E1104 Standard Specification for Clinical Thermometer Probe Covers and Sheaths
- ASTM E1112 Standard Specification for Electronic Thermometer for Intermittent Determination of Patient Temperature
- ISO 10993-1 Biological evaluation of medical devices - Part 1: Evaluation and testing
- ISO 15223-1 Medical devices-Symbols to be used with medical device labels, labeling and information to be supplied
- IEC 62304 Medical device software - Software life-cycle processes
- IEC 62366 Medical devices - Application of usability engineering to medical devices
- IEC 60601-1-1 Medical Electrical Equipment- Part 1-1: General Requirements for Safety - Collateral Standard: Safety requirements for medical electrical systems
- EN 1041 Information supplied by the manufacturer of medical devices

7. **Clinical Studies**

The NIBP and TEMP module of the subject device Accutorr 3 Vital Signs Monitor have been evaluated for clinical accuracy and have been designed to comply with applicable clinical standards. These modules have been tested and evaluated under the following clinical standards:

- ISO 80601-2-56 Particular requirements for basic safety and essential performance of clinical thermometers
- SO 81060-2 Non-Invasive Sphygmomanometers – Part 2: Clinical Validation of Automated Measurement Type

8. **Conclusion:**

The results of all testing demonstrate that the Accutorr 3 Vital Signs Monitor is as safe, as effective, and perform as well as the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

May 16, 2014

Shenzhen Mindray Bio-Medical Electronics Co., Ltd.
c/o Mr. Yanhong Bai
Manager Regulatory Affairs
Mindray Building, Keji 12th Road South, High-Tech Industrial Park,
Nanshan, Shenzhen 518057
P.R. China

Re: K132037
Trade/Device Name: Accutorr 3 Vital Signs Monitor
Regulation Number: 21 CFR 870.2300
Regulation Name: Cardiac monitor (including cardiotachometer and rate alarm)
Regulatory Class: Class II
Product Code: MWI, DQA, DXN, FLL
Dated: May 08, 2014
Received: May 12, 2014

Dear Mr. Bai:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (If known): K132037

Device Name: Accutorr 3 Vital Signs Monitor

Indications for Use:

The monitor is intended for spot-check monitoring physiologic parameters, including SpO2, PR, NIBP and TEMP, on adult, pediatric, and neonatal patients in healthcare facilities by clinical physicians or appropriate medical staff under the direction of physicians.

Prescription Use X _____ **AND/OR** **Over-The-Counter Use** _____
(Part 21 CFR 801 Subpart D) **(21 CFR 801 Subpart C)**

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

FDA Date: 2014.05.16 04'00'